In the Claims:

The following is a complete listing of the claims, intended to replace any claims previously set forth in this matter. Please amend the claims as shown. New claims 295-300 are added.

Claims 1-249 (CANCELLED).

250. (Currently Amended) A proprietary method of use for a product of manufacture or device, wherein the ~~the~~ use was established according to the steps comprising:

accessing one or more data sources, wherein at least one data source comprises adverse event data;

analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;

identifying at least one ~~novel~~ previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential ~~novel~~ adverse event, identifying the at least one ~~novel~~ previously unreported method of use for~~,~~ the product or device;

documenting inventorship of the at least one ~~novel~~ method of use for the product or device; and

creating a database of proprietary essential adverse event information, the database storing data regarding the at least one ~~novel~~ essential adverse event, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, and

wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.

251. (Currently Amended) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprise determining value of commercializing the at least one ~~new~~ use determined from the at least one identified essential adverse event.

252. (Currently Amended) The proprietary method of use of claim 251, wherein the steps of establishing the use further comprise commercializing the at least one ~~novel~~ use.

253. (Currently Amended) The proprietary method of use of claim 252, ~~wherein~~ where in the steps of establishing the use, the commercializing step further comprises generating information for incorporation into documents for selling, leasing or licensing the ~~newly~~ identified product information.

254. (Previously Presented) The proprietary method of use of claim 252, wherein the product is commercially available at the time of the analyzing step.

255. (Currently Amended) The proprietary method of use of claim-252, ~~wherein~~ where in the steps of establishing the use, commercializing further comprises formatting the data relating to at least one ~~novel~~ adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one ~~novel~~ adverse event associated with exposure to or use of the product or device.

256. (Currently Amended) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and ~~wherein~~ where in the steps of establishing the use, the at least one data source comprises information relating to patents and patent applications.

257. (Currently Amended) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and ~~wherein~~ where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

258. (Currently Amended) The proprietary method of use of claim 252, ~~wherein~~ where in the steps of establishing the use, the at least one adverse event comprises a drug interaction.

259. (Currently Amended) The proprietary method of use of claim 258, ~~wherein~~ where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

260. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use of the essential adverse event data are proprietary.

261. (Previously Presented) The proprietary method of use of claim 250, wherein the product is medical.

262. (Previously Presented) The proprietary method of use of claim 252, wherein the product is medical.

263. (Previously Presented) The proprietary method of use of claim 262, wherein the medical product is a generic drug.

264. (Previously Presented) The proprietary method of use of claim 250, wherein the product is non-medical.

265. (Previously Presented) The proprietary method of use of claim 252, wherein the product is non-medical.

266. (Previously Presented) The proprietary method of use of claim 250, wherein the device is medical.

267. (Previously Presented) The proprietary method of use of claim 252, wherein the device is medical.

268. (Previously Presented) The proprietary method of use of claim 250, wherein the device is non-medical.

269. (Previously Presented) The proprietary method of use of claim 252, wherein the device is non-medical.

270. (Currently Amended) A proprietary kit containing a product or device, and labeling notifying a user of at least one ~~novel~~ previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 250.

271. (Currently Amended) A proprietary kit containing a product or device, and labeling notifying a user of at least one ~~novel~~ previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 259.

272. (Currently Amended) The proprietary method of use of claim 250, wherein the ~~novel~~ method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. (Currently Amended) The proprietary method of use of claim 253, wherein the ~~novel~~ method of use ~~as~~ is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event is a drug interaction.

275. (Previously Presented) The proprietary method of use of claim 274, wherein the product or device is commercially available at the time of the analyzing step.

276. (Previously Presented) The proprietary method of use of claim 275, wherein the proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. (Previously Presented) The proprietary method of use of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data.

278. (Currently Amended) The proprietary method of use of claim ~~275~~ 277, wherein at least one ~~novel~~ previously unreported essential adverse event is other than a chronic immune mediated disorder.

279. (Previously Presented) The proprietary method of use of claim 277, the steps further comprising determining value of commercializing the at least one proprietary method of use determined from the at least one identified essential adverse event.

280. (Currently Amended) The proprietary method of use of claim 278, the steps further comprising commercializing the at least one proprietary method of use and the product or device is commercially available, wherein commercializing comprises formatting the data relating to at least one ~~novel~~ previously unreported essential adverse event ~~associated with exposure to, or use of the product or device, or documenting same~~, such that a manufacturer or distributor of the product or device must inform ~~consumers,~~ users ~~or individuals responsible for the user, physicians or prescribers~~ about at least one ~~novel~~ previously unreported essential adverse event ~~associated with exposure to or use of the product or device~~.

281. (Currently Amended) The proprietary method of use of claim 250, wherein at least one ~~novel~~ previously unreported essential adverse event comprises ~~an~~ a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

282. (Currently Amended) The proprietary method of use of claim 252, wherein at least one ~~novel~~ previously unreported essential adverse event comprises ~~an~~ a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

283. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. (Currently Amended) The proprietary method of use of 250, wherein the at least one ~~novel~~ method of use of the product or device is a restricted use in at least one population subgroup, ~~when~~ where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the ~~novel~~

previously unreported essential adverse event is one other than a chronic immune mediated disorder.

286. (Currently Amended) The proprietary method of use of 252, wherein the at least one ~~novel~~ method of use of the product or device is a restricted use in at least one population subgroup, ~~when~~ where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the ~~novel~~ previously unreported essential adverse event is one other than a chronic immune mediated disorder.

287. (Currently Amended) The proprietary method of use of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the ~~novel~~ method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. (Currently Amended) The proprietary method of use of claim 251, wherein the product or device is commercially available, the steps further comprising identifying the ~~novel~~ method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. (Currently Amended) The proprietary method of use of claim 252, wherein the product or device is commercially available, the steps further comprising identifying the ~~novel~~ method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

290. (Currently Amended) The proprietary method of use of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the ~~novel~~ method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. (Previously Presented) The proprietary method of use of claim 250, the steps further comprising documenting date of inventorship.

292. (Previously Presented) The proprietary method of use of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

293. (Currently Amended) The proprietary method of use of claim 250, wherein the product or device is commercially available, and the ~~novel~~ method of use is further identified as comprising restricting exposure of the product or device to at least one ~~of the high risk associated groups~~ factor selected from the group consisting of high temperatures, ~~or~~ low temperatures, chemicals, surfaces, pressures, electricity, ~~and~~ sparks; ~~or~~ contact ~~of the product or device~~ with ~~one of the group~~ an anatomical element selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the ~~consumer~~ user; ~~or~~ exposure to a subpopulation group selected from the group consisting of children, pregnant women, ~~consumers~~ users with specific allergies, ~~or~~ users with specific medical conditions, and animals; ~~or~~ exposure to ~~a subpopulation~~ subpopulations defined by at least one ~~consumer~~ user-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, ~~and~~ use of drugs, ~~diet,~~ use of tobacco, use of alcohol, ~~or~~ and use of medical devices.

294. (Previously Presented) The proprietary method of use of claim 250, wherein at least one database of essential adverse event information is computerized.

295. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises accessing one or more data sources, wherein at least one data source comprises human adverse event data.

296. (Currently Amended) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises utilizing least one controlled clinical trial and or epidemiological study to discover at least one ~~novel~~ previously unreported essential adverse event.

297. (Previously Presented) The proprietary method of use of claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. (Currently Amended) The proprietary method of use of claim 250, wherein the ~~novel~~ use is one other than a new dosing regimen.

299. (Currently Amended) The proprietary method of use of claim 250, wherein the ~~novel~~ use further comprises providing ~~novel~~ printed product safety information in connection with product packaging.

300. (Currently Amended) The proprietary method of use of claim ~~250~~ 252, wherein the ~~novel~~ use further comprises providing ~~novel~~ printed product warning information in connection with product packaging.